
**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

JANE DOE, on behalf of herself and
her minor child SARAH DOE,

Plaintiffs,

-against-

Civil Action 2:21-cv-5012

FRANKLIN SQUARE
UNION FREE SCHOOL
DISTRICT, and MARY
T. BASSETT in her
official capacity as
Commissioner of the
New York State
Department of Health.

Defendants.

**MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS**

ORAL ARGUMENT REQUESTED

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PRELIMINARY STATEMENT

Plaintiff Jane Doe (“Jane”) is the mother of Sarah Doe (“Sarah”), a ten-year-old child with disabilities including asthma and anxiety, which prevent her from medically tolerating a mask. [ECF No. 33 ¶ 1]. Jane brings this action on behalf of herself and Sarah against the Franklin Square Union Free School District (the “District”) and Commissioner of the New York State Department of Health (“NYSDOH”) acting in her official capacity (Commissioners – prior and current – collectively referred to as “Commissioner”).

Defendants' motions to dismiss (“District’s Motion” and “State’s Motion”) Plaintiffs’ Amended Complaint (“Complaint”) each offer alternative (unsworn) facts, citations to cases that fail to support their arguments (or have been overruled), and straw-man arguments against issues not central to this case. Because the Complaint pleads viable claims for relief, Plaintiffs respectfully request that the Court deny the pending motions to dismiss and order Defendants to file their answers.

STATEMENT OF FACTS

A comprehensive statement of the relevant facts is contained within the Amended Complaint, incorporated herein by reference. [ECF No. 33]. In short, during the 2020-2021 school year, the Commissioner issued a series of mask mandates for school children, each stating “[s]tudents who are unable to medically tolerate a mask, including students where such mask would impair their physical or mental health are not subject to the requirement of a mask.” [ECF No. 33 ¶ 23]. It quickly became apparent that Sarah could not medically tolerate a mask and that the use of masks was impairing her physical, emotional, and mental health. [ECF No. 33 ¶ 2].

When Jane addressed this issue with the school, Sarah was summarily denied accommodation by District Superintendent Jared T. Bloom (“Superintendent Bloom”), who informed Jane that the District’s official policy was to deny all medical exemptions. ECF No. 33 ¶ 43. Jane attempted for months to get clarity and a decision in writing but was continuously met with obstinate and unlawful refusal by the District to consider any reasonable accommodation, even the accommodation of allowing Sarah to join the remote classes then offered to other students. [ECF No. 33]. Rather than attempt to accommodate Sarah, the District retaliated against her. Employees filmed and denigrated her, and even the principal encouraged and joined in the harassment. [ECF No. 33 ¶¶69-70]. The School District Doctor intentionally misrepresented his conversation with Sarah’s doctor, prompting Sarah’s doctor to write a clarifying (and indignant) letter back clarifying that Sarah needs an exemption and the District doctor nonetheless overruled his decision against medical advice. [ECF No. 33 ¶58-64]. Meanwhile, Sarah’s health deteriorated to an alarming degree. Her asthma attacks became more frequent, her grades (which had always been excellent before) deteriorated, she suffered from migraines, dizziness, and anxiety causing her to lose so much weight that her doctor recommended she join a program for underweight children to try to gain weight; eventually, the anxiety and difficulty breathing became so bad that Sarah’s hair started to fall out in clumps. [ECF No. 33 ¶¶25,26,32-37,68-73,98-99].

At the end of the Spring semester 2021, the old mask mandate was rescinded. But in August 2021, Howard Zucker (“Commissioner Zucker”), who was at the time the Commissioner of the New York State Department of Health (“NYSDOH”), announced a new school mask mandate for the upcoming 2021-2022 school year for all students “able to medically tolerate a face covering/mask” (the “Mandate”). [ECF No. 33 ¶ 3]. The Mandate specifies that it “is subject to applicable CDC-

recommended exceptions” and states “nothing in this determination shall be interpreted as inconsistent with the Americans with Disabilities Act (ADA), workplace safety guidelines, or applicable federal regulations.” [Gibson Decl. Ex. 1]. Additional Guidance provided that “People with medical or developmental conditions that prevent them from wearing a mask may be exempted from mask requirements, as documented by a medical provider” and reiterated the requirement that school districts comply with the ADA. [Gibson Decl. Ex. 2].

On August 24, 2021, Sarah submitted another letter from her doctor certifying that Sarah required an exemption in accordance with the Mandate’s guidance. [ECF No. 33 ¶ 4]. Once more, the District summarily denied accommodation. The school district’s attorneys stated that the District’s doctor (who has never treated Sarah and is an Osteopath without expertise in her conditions) based the denial decision on a Centers for Disease Control and Prevention (“CDC”) webpage: “in its guidance dated April 7, 2021, the CDC has taken the position that people with moderate to severe asthma are at increased risk to be hospitalized for COVID-19 and therefore should wear a mask...to reduce the risk of severe illness.” [ECF No. 33 ¶87]. The webpage relied upon is not evidence-based, and nothing contained in the vague paragraphs provides a reasonable basis for concluding that all children with asthma and anxiety can safely wear a mask all day at school and should be denied accommodation. In fact, the page concludes that people should talk to their healthcare provider if they experience difficulty wearing a mask, presumably to decide whether they can safely continue to wear a mask. [ECF No. 33 ¶¶87-93]. Plaintiff asserts that it is not safe to substitute non-specific and generalized webpage statements for the advice of her treating physician, who has treated her since birth and is uniquely qualified to make a medical determination about what she can safely tolerate. *Id.*

School district attorneys later admitted in court that the District’s official policy only allows accommodation for paraplegic students. [ECF No. 33 ¶ 44]. In the District’s moving papers, attorneys reveal the irrationality of the district’s “paraplegic only” policy, by asserting it is derived from random CDC statements which acknowledge a subset of children with disabilities who cannot safely or effectively tolerate a mask and states: “... for example, a person with a disability who, for reasons related to the disability would be physically unable to remove a mask without assistance if breathing becomes obstructed, should not wear one.” District Motion to Dismiss, p.5. While this example would seem to encompass paraplegics, nothing about the guidance could reasonably lead to the conclusion that only paraplegics might need a mask exemption. Moreover, the CDC pages hyperlinked from the Mandate itself encourage people to talk to their healthcare provider to determine if they need exemptions in cases where they experience dizziness, trouble breathing or other symptoms that Sarah faces from prolonged mask use.¹ It is reasonable to infer that this indicates the CDC’s recommendation that these decisions should be made on an individual basis by trusted treating physicians. The Complaint asserts, and Plaintiff intends to prove, that no peer-reviewed science or even CDC recommendation supports the District’s policy of refusing to accommodate any child but a paraplegic or of overruling treating physicians about the necessity of a mask exemption. Id at ¶ 45. Because of the District’s medical exemption policies, Sarah and other

¹ https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fprevent-getting-sick%2Fcloth-face-cover-guidance.html

children who require accommodation pursuant to law are being denied reasonable accommodation from the mask mandate. ECF No. 33 ¶ 8.

1. The Evidence Does not Support an Inference that Masks are Safe or Effective

A shocking dearth of studies have been conducted to ensure that masks are safe or effective for prolonged use in children, particularly children with Sarah’s disabilities. Existing peer-reviewed data (mostly done on adult populations) tends to show that masks are not effective at reducing the spread of COVID-19 and can cause harm. [ECF No. 33 ¶¶100-160]. Most European countries do not mask children because of the acknowledged risk of harm to learning, and increased depression, anxiety, and health impacts that prolonged mask use in children can cause. [ECF No. 33 ¶¶ 144-160]. The CDC faces enormous criticism for promoting shoddy “observational” studies supporting face masks in schools that have now been thoroughly debunked and discredited, even by pro-mask outlets. [ECF No. 33 ¶¶123-27].² Even the NYSDOH has long acknowledged the dearth of science supporting either efficacy or safety of mask use in schools. [ECF No. 33 ¶¶54-57].

2. All Masks are, by Statutory Definition, Experimental Medical Products

Masks are, by statutory definition, experimental medical devices when used for the purpose of virus mitigation. All masks used for a medical purpose (including protection from spread of disease) are “regulated medical devices” pursuant to section 201(h) of the Food, Drug and Cosmetic Act (“FDCA”). As noted in the Complaint, and contrary to Defendants’ unsupported assertions, the Food and Drug Administration (“FDA”) has not licensed any mask for children or use in schools for

² As an ancillary point, the ongoing studies of the effectiveness of masks in schools, while poorly designed, do show that school children are the subject of ongoing scientific experimentation and study to attempt to gather data about whether an experimental medical device is effective.

this purpose. This includes not only cloth masks, but also surgical masks and respirators including N95 and KN95 masks. [ECF No. 33 ¶¶161-164]. The FDA has authorized limited use of masks outside of hospitals only under “Emergency Use Authorization” (“EUA”). The terms of the governing EUA’s all state that it is unlawful to force or coerce use of a mask for virus mitigation, or to claim that masks are safe and effective to stop the spread of COVID-19. [ECF No. 33 ¶¶161-172]. Contrary to Defendants’ assertion, no surgical mask has even been authorized, even under EUA, by the FDA for use in schools by children, and neither has any respirator, including N95 or KN95. In fact, FDA revoked the EUA for KN95s, even for adults.³ N95’s were never authorized for use by children under EUA (or any other authorization) either. Both CDC and FDA caution that “N95 respirators are not designed for children” and can exacerbate breathing problems in people with underlying issues.⁴ As the complaint points out, cloth masks, which do have an EUA allowing use for children, are ineffective and by the terms of their use cannot be coerced or labeled as effective at stopping the spread of viruses. [ECF No. 33 ¶¶161-172].

3. Sarah Can be Accommodated without Posing a Direct Threat

Sarah does not pose a “direct threat” to anyone because of her need for accommodation from the Mandate. [ECF No. 33 ¶¶161-172]. The bulk of the data and evidence (and the near consensus of scientists) now recognize that masks are not capable of stopping the spread of COVID-19 and that prolonged mask use can cause harm to many children. [ECF No. 33 ¶¶100-160]. Even if

³ <https://www.fda.gov/news-events/press-announcements/fda-brief-fda-revokes-emergency-use-authorizations-certain-respirators-and-decontamination-systems>

⁴ See, e.g. <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-face-masks-and-barrier-face-coverings>.

masking were more effective, allowing Sarah an exemption cannot create a significant risk of substantial harm to any of her classmates. *Id.*

The Mandate itself contemplates and requires exemptions, leading to the reasonable inference that giving such exemptions does not create a direct threat to others. [ECF No. 33 ¶¶161-172]. Moreover, the District itself essentially allowed Sarah an exemption when it allowed her to wear a “mesh mask” to avoid a hearing and potential adverse decision from this Court. In making the accommodation, the District acknowledged that mesh masks provide no protection from the spread of COVID-19. *Id.*

ARGUMENT

I. Standard of Review.

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’ *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678.

A court, in deciding a 12(b)(6) motion, must “accept well pleaded factual assertions as true; and [] draw all reasonable factual inferences in favor of the plaintiff.” *Lynch v. City of New York*, 952 F.3d 67, 74–76 (2d Cir. 2020); *see also*, *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 230 (2d Cir. 2016) (a court is “not bound to accept as true a [pleading’s] legal conclusion,” but “for the purposes of a motion to dismiss [it] must take all of the factual allegations in the complaint as true.” The court must also “construe all reasonable inferences that can be drawn from the complaint in the light most favorable to the plaintiff.”) “The assessment of whether a complaint’s factual allegations plausibly give rise to an entitlement to relief “does not impose a probability requirement at the

pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal” conduct. *Lynch*, 952 at 76 (citing *Iqbal*, 556 U.S. at 678). The choice between two plausible inferences that may be drawn from factual allegations is not a choice to be made by the court on a Rule 12(b)(6) motion. “Rule 12(b)(6) does not countenance ... dismissals based on a judge's disbelief of a complaint's factual allegations.” *Twombly*, 550 U.S. at 556 (internal quotation marks omitted).

Normally, facts considered are limited to those pleaded on the face of the Complaint and reasonable inferences concluded therefrom. “Courts may take judicial notice of certain publicly available documents. . . [b]ut they must do so ‘to determine what statements [the documents] contained . . . [and] not for the truth of the matters asserted’ in the documents.” *Lewis v. M&T Bank*, 2022 U.S. App. LEXIS 6596, at *3 (2d Cir., Mar. 15, 2022, No. 21-933) (2022). To the extent this Court considers any documents or facts introduced from outside of the Complaint, these documents cannot be relied upon to resolve disputed factual questions in Defendants’ favor, as Defendants propose.

II. The Mandate Violates Plaintiffs’ Fundamental Rights

Plaintiff alleges that the Mandate, as applied by the State and District, violates her fundamental constitutional rights. When a state’s exercise of such police powers infringes a fundamental right, the state action must be narrowly tailored to serve a compelling interest. *Reno v. Flores*, 507 U.S. 292, 302 (1993). A right is fundamental if it is “implicit in the concept of ordered liberty,” *Palko v. Connecticut*, 302 U.S. 319, 325-26 (1937), or “deeply rooted in this Nation’s history and tradition,” *Moore v. E. Cleveland*, 431 U.S. 494, 503 (1977).

The central constitutional question in this case is whether families have a fundamental right

to a medical exemption from state laws mandating use of an experimental medical product in cases where the child's physician has certified that the experimental product is causing or is likely to cause the child serious harm. This question implicates many fundamental rights, each of which triggers strict scrutiny review in its own right.

A. There is a Fundamental Right to Self-Defense

Plaintiff asserts that she has a fundamental right to a medical exemption because the Mandate is causing her significant physical harm. The right to defend oneself from state action which causes bodily harm is grounded not only in fundamental liberty interests, but in the right to life itself. It is a natural right, deeply rooted in our foundational concepts of law and justice and is considered by scholars as antecedent to the validity of any governmental system. See, e.g., A.J. ASHWORTH, SELF-DEFENCE AND THE RIGHT TO LIFE, 34 Cambridge L.J. 282, 282 (1975). John Locke discussed self-preservation from infringements on the right to one's bodily security as being so fundamental to basic human nature that "no law can oblige a man to abandon it." *Id.* (citing JOHN LOCKE, SECOND TREATISE OF GOVERNMENT, Ch II, 6, 1690). In his Commentaries on the Laws of England, William Blackstone described the right to protect one's "life and limb" from harm as "the primary law of nature," holding that it is an "absolute right" which "every man has a right to enjoy." *Id.* (citing 1 W. BLACKSTONE, COMMENTARIES 119).

It is not surprising, then, that for over a hundred years at least, the Supreme Court has recognized a sufficient medical exemption as a constitutional prerequisite to any valid public health law. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 27, 36-39 (1905). In *Jacobson*, the Court held that the state's compelling interest in protecting the community outweighed Plaintiff's unspecified liberty interests in being free of a \$5 fine for refusing a smallpox vaccine during a

raging pandemic. *Id.* But, the Court cautioned repeatedly that the state’s police powers are not unlimited and that “even if based on the acknowledged police powers of a state,” a public-health measure “must always yield in case of conflict with...any right which [the Constitution] gives or secures.” *Id.* at 25. The sole specific example of such a conflict offered by the Court was that it would be ‘cruel and inhuman in the last degree’ to require someone to be vaccinated “if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination, or that vaccination, by reason of this then condition, would seriously impair his health or probably cause his death.” *Id.* at 39. This distinction is not about the statutory source of a health exemption. It is about the Court’s ability to interfere if a statute infringes a person’s constitutional right to protect themselves from significant risk of harm to health or life. “We are not to be understood as holding that the statute was to be applied to such a case, or if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned.” *Id.*

Public health law scholars acknowledge the strict principle of harm avoidance as part of the foundational holding of *Jacobson*. See, e.g., LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 126-28 (2d ed. 2008) (per *Jacobson*, public health regulations require five elements to be constitutional: (1) public health necessity, (2) reasonable means, (3) proportionality, (4) harm avoidance, and (5) fairness). The Supreme Court’s medical exemption cases since *Jacobson* consistently uphold the harm avoidance principle, clarifying that, if a medical exemption is narrow enough to exclude even a few who might need it, it is unconstitutional on its face. See, e.g., *Stenberg v. Carhart*, 530 U.S. 914, 937 (2000); *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320 (2006).

The medical exemption right in abortion cases is not derived, as Defendants argue, from the liberty right to an abortion. It cannot be, for the medical exemption cases arise in contexts in which the abortion right has been overcome by the state's compelling interests. If the right to a medical exemption was simply derived from the liberty interest in abortion, it would be overcome as well. Rather, "the health exception vocalizes a principle of negative liberty--to be free from state-imposed physical harms--that precedes and stands separate and apart from [the abortion right]." Elyssa Spitzer, *Pregnancy's Risks and the Health Exception in Abortion Jurisprudence*, 22 Geo. J. Gender & L. 127, 146 (2020).

In *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992), the Supreme Court cited *Jacobson's* harm avoidance principal to note that the right to a medical exemption was likely rooted in the right to refuse medicine and safeguard one's person, rather than the right to privacy articulated as the foundation of the abortion right. *Id.* at 857 ("Roe, however, may be seen not only as an exemplar of *Griswold* liberty but as a rule...of personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or bar its rejection. If so, our cases since *Roe* accord with *Roe's* view that the State's interest in the protection of life falls short of justifying plenary override of individual liberty claims." (citing *Cruzan*, 497 U.S. at 278; *cf.*, e.g., *Riggins v. Nevada*, 504 U.S. 127,135 (1992); *Washington v. Harper*, 494 U.S. 210 (1990); see also, e.g., *Rochin v. California*, 342 U.S. 165 (1952); *Jacobson*, 197 U.S. at 24-30.) The *Casey* plurality recognized that "[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to possession and control of his own person" *Id.* But, like *Jacobson*, the Court particularly protected a woman's right to defend herself from infringements on bodily integrity that can cause her harm – in

such cases, the right to bodily integrity appears nearly absolute. *Id.*; see also, *Stenberg*, 530 U.S. at 937 (facially striking a partial abortion law that even left open the possibility that a woman whose health was at risk could be denied the protection of a medical exemption).

Indeed, most laws give way when a person is acting to protect herself from imminent harm. Contract law finds formal agreement absent if a person was compelled to consent, under duress of threat to physical health; and physically harming another person, though generally prohibited, is an affirmative defense in criminal law and is justified if the harm was inflicted in self-defense. *See, e.g.,* Carl Graff, *The Religious Right to Therapeutic Abortions*, 85 GEO. WASH. L. REV. 954, 958-69 (2017) (arguing that the health exception is rooted in self-defense rights and “is an alternative avenue to maintain the right to health exceptions for abortion”). This concept of self-defense is fundamental to the structure of common law, and in turn, forms the bedrock of the social contract woven into Constitutional guarantees. *See, Anita L. Allen, Social Contract Theory in American Case Law*, 51 FLA. L. REV. 1, 33-34 (1999).

B. There is a Fundamental Right to Refuse an Experimental Medical Product.

As the *Casey* decision articulates, the medical exemption right is also derived from the fundamental right to refuse medical treatment. It is well-settled law that a competent person has a fundamental right to refuse unwanted medical treatment, even lifesaving preventative “treatment” such as food and water. *Cruzan by Cruzan v. Dir., Missouri Dep’t of Health*, 497 U.S. 261, 110 (1990). As this Court acknowledged, “[t]here is no question that the right [to refuse medical treatment] is fundamental.” [ECF No. 26 at 42]. *See, e.g., Washington v. Glucksberg*, 521 U.S. 702, 722 n. 17 (1997) (“In [*Cruzan*], we concluded that the right to refuse medical treatment was so rooted in our history, tradition, and practice as to require special protection under the Fourteenth

Amendment.”).

Your Honor posited that there may be a carve out from the well-established fundamental rights because masks might be likened to shoes or helmets rather than medical treatment to be refused. Plaintiffs respectfully ask the Court to reconsider this position and the factual inferences in favor of Defendants that undergird it. Neither motorcycle helmets nor shoes are regulated medical devices. Masks, on the other hand, are defined by congress as regulated medical products whenever they are used for a medical purpose, including to mitigate the spread of COVID-19. Additionally, the FDA, which exercises regulatory authority over masks used for medical purposes, specifically declined to license any mask for use in schools by children, despite the severity of the pandemic. Rather, they only allow limited use of certain types of cloth masks under the strict confines of Emergency Use Authorization (“EUA”). Masks are thus not only regulated medical devices—they are, by statutory definition, *experimental* medical products. As this Court acknowledges, “our country is being challenged to rationally decide how to best protect the health of our children in uncharted waters that make all of us medical guinea pigs. Indeed, there is no conclusive study as to either the short-term or long-term effects that mask wearing could have on children.”

This is precisely why it is vital that we safeguard children’s fundamental rights in this context. The right to refuse *experimental* medical interventions is not just a fundamental constitutional right. The Second Circuit recognizes this right as so universally recognized and fundamental as to arise to the level of a *jus cogens* norm. *See, e.g., Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 184 (2d. Cir. 2009) (citing “[t]he Nuremberg Code, Article 7 of the ICCPR, the Declaration of Helsinki, the Convention on Human Rights and Biomedicine, the Universal Declaration on Bioethics and Human Rights, the 2001 Clinical Trial Directive, and the domestic

laws of at least eighty-four States" to define the right to informed consent to use experimental medical products as a *jus cogens* norm). Certainly, a *jus cogens* right rises to the level of that type of right "implicit in the concept of ordered liberty" as to also constitute a fundamental right for purposes of constitutional analysis.

While the state's police powers are important, they must be strictly scrutinized when they cross the boundaries of fundamental constitutional and human rights to ensure that they are necessary and appropriately tailored. The horrors that would ensue if invocation of the police power were sufficient to trample such sacred and basic rights without serious examination or limit are precisely why we codified this *jus cogens* norm into the very fabric of our international, federal, state, and local laws. Invoking the protection of codified laws is different from making false equivalents. If lawmakers intended courts to bury these rights and considerations in history, and never uphold them outside of the context of the Holocaust, they would not have codified them into binding international, federal, state and local law.

C. Fit Parents have a Fundamental Right to Make Medical Decisions for their Children in Accordance with a Licensed Physician's Recommendation.

The challenged state-action also violates fundamental parental rights. Fit parents have a fundamental right to make medical decisions on behalf of their minor children. *Parham v. J.R.*, 442 U.S. 584 (1979); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925). "[T]he interests of parents in the care, custody, and control of their children is perhaps the oldest of the fundamental liberty interests recognized by this Court." *Troxell v. Granville*, 530 U.S. 57, 65 (2000). "Simply because the decision of the parent ... involves risks does not automatically transfer the power to make that decision from the parents to some agency or officer of the state. The same characterizations can be made for a tonsillectomy, appendectomy, or other medical procedure ... Parents can and must make

those judgments...Neither state officials nor federal courts are equipped to review such decisions.” *Parham*, 442 U.S. at 604.

The Fundamental Right of parents to make medical decisions for their child adhere not only to the parent but to the child as well. “The right to family association includes the right of parents to make important medical decisions for their children, and of children to have those decisions made by their parents rather than the state.” *Wallis v. Spencer*, 202 F.3d 1126, 1141 (9th Cir. 2000). Here, there is no allegation that Jane is unfit, and she (and her child) logically wish to follow the advice of Sarah's trusted treating physician, which is a protected fundamental right in and of itself.

Defendants suggest that this right is diminished when a child walks through the schoolhouse door. But the cases cited for this proposition are inapposite. Those cases deal with a parents’ right to interfere in the schools’ determination of appropriate subject matter to teach to children in public schools, which is within their mandate. While a parent certainly has a right to decide whether to send a child to public or private school, *see, Pierce*, 268 U.S. at 510, this right does not extend to “requiring a public school to establish that a course of instruction objected to by a parent was narrowly tailored to meet a compelling state interest.” *Leebaert v. Harrington*, 332 F.3d. 134, 141 (2d Cir. 2003). However, such a limitation is entirely distinct from conditioning the right of a child to attend a school on the waiver of the parental right to decline medical treatment that causes harm to a child. Such a condition violates the unconstitutional conditions doctrine, as discussed *supra*, and likely also violates the right of a parent to send their child to public school. Schools are not qualified or tasked with making medical decisions for their students, and these fundamental rights are clearly reserved to parents not school administrators.

D. There is a Fundamental Right to Receive Medical Care in Accordance with a Chosen Licensed Physician's Independent Medical Judgment.

Medical exemptions implicate another important fundamental right – that is, the right of patients to make medical decisions in accordance with their doctors' independent good faith medical judgment. In *Doe v. Bolton*, 410 U.S. 179 (1973), the Supreme Court held that it is unconstitutional for a state to subject medical exemption determinations issued by a state licensed physician to state or third-party review. The Court acknowledged that the state and hospitals had good reasons to want to review medical exemption determinations given the important interests the state has in protecting life after viability, among other considerations. However, the “woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited” by allowing such reviews to take place. The Court balanced the state's interests against this right by holding that “if a physician is licensed by the State, he is capable of exercising acceptable clinical judgment” and no further state interference in the medical exemption determination can infringe the fundamental rights of the patient. *Id.* At 192.

Sarah's medical exemption was written by her state-licensed physician and must be honored by the state without further interference pursuant to the Court's precedent in *Doe*. Defendants' attempt to distinguish *Doe* from this case by claiming that the Court's holding applies only to abortion cases. These arguments are misplaced. The Supreme Court expressly reaffirmed *Doe* outside of the abortion context in *Whalen v. Roe*, 429 U.S. 589, 603 (1977).

As this Court noted, the right to make medical decisions free of state interference is not unlimited. The state is involved in licensing and disciplining doctors. The federal government is empowered, for example, to regulate medical products and controls licensing of available products. Vigorous debate exists about whether the constitution protects a person who seeks access to a drug

that is not available to the public in cases where the patient claims they need it to safeguard their health. For example, proponents of medical marijuana claim a right to positive access to illegal drugs as derivative of the right to refuse medication. Whether courts should extend the right that far, however, does not impact this case. Here, the question is particularly uncomplicated because the Mandate itself calls for medical exemptions and the guidance even provides that the exemptions should be given if a child presents a letter from a healthcare provider. The District's official policy of denying all applications for medical exemptions other than for paraplegics, and its official policy and decision to substitute its judgment for that of Sarah's state-licensed doctor and deny her a medical exemption based on generalized statements found online, are precisely the type of unconstitutional infringement on the doctor-patient decision making articulated in *Doe* and affirmed as unconstitutional in *Whalen*. Claims against the State remain, because as articulated in *Ayotte*, when a medical exemption is regularly applied in a manner resulting in a risk that meritorious claims will be denied, the Court must decide whether to strike the entire regulation, or issue declaratory relief that would prevent further unconstitutional application. Either way, such relief would need to attach to the State's regulation. Moreover, according to the District Defendants, the state "required" them to substitute their judgment for Sarah's provider based on non-individualized "guidance" from a CDC webpage interpreted by the State and District as requiring discriminatory denial against most children's medical exemption applications. State Defendants do not deny this. In fact, they admit it is true and argue it should be. [Gibson Decl. Ex 3, pp. 22-25]. Given these admissions, dismissal is not warranted at this stage against either party.

Defendants assert that treating physicians and parents should not be permitted to make medical necessity decisions, because they are overfocused on the best interests of the child and may

not balance the needs of the community. However, medical necessity has nothing to do with the needs of the community and it is precisely to avoid this type of utilitarian blurring of the lines that the Courts uphold the fundamental right of patients to be free of state intervention in these decisions and instead to make them with their chosen physician. The state's interest are not balanced at the stage of determining medical necessity. The state's interests become relevant in applying strict scrutiny once a threshold claim has been made that a child is at risk of harm from a public health law, which triggers strict scrutiny when she is denied accommodation by the state. If the state indeed has a compelling reason to deny a child accommodation even though such denial places her life or health at risk, they must be prepared to defend that decision in court. *Jacobson*, 197 U.S. at 39.

Similarly, Defendants' arguments that the *Doe* and *Whalen* can be distinguished because the medical decisions only impact the individuals in those cases, are factually incorrect. The central tension in an abortion case is that another life hangs in the balance. In *Doe*, the whole point was that an overbroad medical exemption policy would certainly lead to the avoidable killing of many viable children. The Court took the state's compelling interest in safeguarding these children's lives very seriously in striking the balance of requiring the exemption to be based on the recommendation of a state-licensed physician. Similarly, opioid abuse does not only impact the addict. The detriment to society is well-documented as well. By contrast, the dangers to third parties are far less stark here. In this case, even Defendants admit that Sarah does not pose a direct threat to others when accommodated. In any event, the appropriate place to address these distinctions is during the application of strict scrutiny, not in the determination of whether strict scrutiny applies.

E. The Unconstitutional Conditions Doctrine Bars Defendants' Defense

Defendants next argue that because they are not using physical force to require Sarah to

wear a mask, her fundamental rights are not burdened because she can simply move or forego an education. The Supreme Court already rejected this argument in 1943 when it held that a West Virginia Board of Education requirement that all children participate in the pledge of allegiance was unconstitutional and must be struck down. *W. Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943). In *Barnette*, as here, the penalty for noncompliance was expulsion from school until a child or family was willing to waive their rights and salute the flag. The fact that a family could still educate their child at home and thereby exercise their right was irrelevant to the Supreme Court in striking down the regulation. “There is no mysticism in the American concept of the State or of the nature or origin of its authority. We set up government by consent of the governed, and the Bill of Rights denies those in power any legal opportunity to coerce that consent.” *Id.* at 641.

Barnette stands as an early example of the well-entrenched unconstitutional conditions doctrine. The unconstitutional conditions doctrine “vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up.” *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). It matters not whether the benefit is a fundamental right. “[E]ven though a person has no ‘right’ to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests.” *Perry v. Sindermann*, 408 U.S. 593, 597 (1972). At base, the “government is not allowed to do indirectly what it cannot do directly in conditioning a government benefit.” *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205 (2013). If it is the case, as Defendants concede, that the government cannot

constitutionally force Sarah to wear an experimental mask against medical advice, then it is also unconstitutional to coerce Sarah to waive her right to a medical exemption to attend school.

In his concurring opinion in the recent *Roman Catholic Diocese* case, Justice Gorsuch pointed out that the level of coercion in conditioning a benefit is highly relevant: “[In *Jacobson*] individuals could accept the vaccine, pay the [\$5 (about \$140 today)] fine, or identify a basis for [medical] exemption. The imposition on Mr. Jacobson's claimed right to bodily integrity, thus, was avoidable and relatively modest. It easily survived rational basis review, and might even have survived strict scrutiny, given the [medical exemption] opt-outs available.” *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 71 (2020). By contrast, whether a state’s total deprivation of access to any public or private school is “settled as not violating fundamental” rights (or not⁵), the deprivation of educational rights is certainly coercive because, “in these days, it is doubtful that any child may reasonably be expected to succeed in life if he is denied the opportunity of an education.” *Brown v. Board of Education of Topeka*, 347 U.S. 483 (1954).

F. Public Health Cases are Not Exempt from Strict Scrutiny

For decades, lower courts misapplied *Jacobson* as establishing carte blanche authority for administrative agencies to avoid judicial review in cases. But in *Roman Catholic Diocese v. Cuomo*, 141 S. Ct. 63 (2020) the Supreme Court overturned this bad precedent to clarify that there is no exception to strict scrutiny in cases intersecting with public health. *Id.* As the Second Circuit recently acknowledged, “the Jacobson Court itself specifically noted that ‘even if based on the

⁵ Plaintiffs do not concede this point. As the Supreme Court held in *Plyler v. Doe*, 457 U.S. 202 (1982), total deprivation of access to school is entitled to at least some vigorous review, particularly given the devastating impact it has on children. “The deprivation of public education is not like the deprivation of some other governmental benefit.” *Id.*, 457 U.S. at 202–03.

acknowledged police powers of a state,’ a public-health measure ‘must always yield in case of conflict with . . . any right which [the Constitution] gives or secures.’” *Agudath Isr. v. Cuomo*, 983 F.3d 620, 635 (2d Cir. 2020) (quoting *Jacobson*, 197 U.S. at 25). In so holding, the Supreme Court and the Second Circuit did not limit this rejection of the substantial relation test to free exercise cases. *Agudath*, 983 F.3d at 635 (quoting *Roman Cath. Diocese*, 141 S. Ct. at 70 (Gorsuch, J., concurring) (“*Jacobson* hardly supports cutting the Constitution loose during a pandemic.”)) *Agudath* clarifies that the substantial relation test, and the notions of deference tied up with it are no longer good law. *Id.* As *Jacobson* presciently warned, courts can and must strictly scrutinize public health decisions that infringe fundamental Constitutional rights. The Supreme Court recently clarified that overbroad deference in such cases will no longer be tolerated. Specifically, Chief Justice Roberts clarified that earlier comments from an overruled concurrence had been misapplied by lower courts. *See, e.g., S. Bay United Pentecostal Church v. Newsom*, 141 S. Ct. 716, 717 (2021) (Roberts, J Concurring) (clarifying that his statements at an earlier stage of the case had been misconstrued regarding deference in public health cases “I adhere to the view that the ‘Constitution principally entrusts the safety and the health of the people to the politically accountable officials of the States.’ **But the Constitution also entrusts the protection of the people's rights to the Judiciary. Deference, though broad, has its limits.**”) (emphasis added). The concurrence collectively issued by Justices Gorsuch, Alito and Thomas leaves little doubt that the Supreme Court no longer tolerates deviation from strict scrutiny based on public health:

In cases implicating this form of “strict scrutiny,” courts nearly always face an individual’s claim of constitutional right pitted against the government’s claim of special expertise in a matter of high importance involving public health or safety. . . . The whole point of strict scrutiny is to test the government’s assertions, and our precedents make plain that it has always been a demanding and rarely satisfied standard. Even in times of crisis—perhaps especially in times of crisis—we have a

duty to hold governments to the Constitution.

Id. at 718 (citations omitted).

G. The Challenged Policies Cannot Survive Judicial Review

A government policy can survive strict scrutiny if it advances interests of the highest order and is narrowly tailored to achieve those interests. *Fulton v. City of Philadelphia*, 593 U.S. ____ (2021). So long as the government can achieve its interests in a manner that does not fundamental rights, it must do so, in order to survive strict scrutiny. *Id.* Here, the government bears the burden of establishing that its actions are narrowly tailored to survive strict scrutiny. Defendants cannot meet this high bar and have not even tried to assert that they can in their moving papers.

It is unlikely that the District's policies can even meet demands of rational basis review. The state Mandate allows for medical exemptions for any child who cannot medically tolerate a mask and has submitted a physician's letter. It is irrational and dangerous for the District to adopt a policy of summarily denying all children other than paraplegics based on generalized website statements cited by Defendants. Moreover, masks cannot stop the transmission of COVID-19, and are also not licensed medical products, but only authorized under EUA. Regardless of standing under the preemption doctrine, the State and District's decisions to mandate experimental medical devices that, by law, are not supposed to be mandated are relevant to determining the rationality of the government's mask policies as applied to Sarah.

III. Plaintiffs' Preemption/EUA Claim Against All Defendants Survives

The Mandate is preempted by federal law, which prohibits coerced use of any EUA product. Preemption, rooted in the Constitution's Supremacy Clause, provides that federal statutes "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. As a threshold matter,

Defendants assertion that surgical masks and respirators are not required to be regulated by the FDA and thus not subject to its limitations is plainly wrong and is also a contested fact, as more fully discussed *infra* in the facts section. For purposes of this motion, the Court must resolve the issue in favor of Plaintiffs.

Next, Defendants argue that the Supremacy Clause “is ‘not the source of any rights and certainly does not create a cause of action.’” *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 325 (2015). But the Clause acts as “a rule of decision,” establishing that federal law prevails over state law when the two conflict, meaning that every preemption question is not one that reflexively prevents standing but turns on questions of statutory construction. *Murphy v. NCAA*, 138 S. Ct. 1461, 1479 (2018) (quotation marks omitted); *Morales v. TWA*, 504 U.S. 374, 383 (1992) (“The question, at bottom, is one of statutory intent, and we accordingly begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.”) (quotation marks omitted)). Here, as more fully addressed in the facts, the plain language of the statute, legislative history and agency interpretations show that Congress intended to provide an individual right to exercise informed consent (or refusal) of any EUA product.

A. The Governing Statutes Secure a Right to Informed Consent

On its face, Federal law prohibits mandatory use of EUA products, including masks, for civilians. Section 564 of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 360bbb-3, 1 (“Section 564”) governs all EUA products. Pursuant to this section, the FDA’s grant of an EUA is subject to informed consent requirements to “ensure that individuals to whom the product is

administered are informed” that they have “the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.” 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). This statutory language requiring that providers inform recipients of their right “to accept or refuse” an EUA product frames an individual’s choice and indicates that individuals have standing to challenge the denial of the right to refuse.

Defendants assert that the intended “consequences” of refusing should include consequences such as lack of access to school, transportation or work in case the product is mandated. But this would render segment one meaningless. Under canons of statutory interpretation, one segment of the statute should not be interpreted to obstruct another. “Rather, provisions, in context, the most plausible interpretation is that “consequences” refers exclusively to the health risks of accepting or refusing an EUA product during a pandemic – not to allowable coercive measures related to refusal. *See, e.g.,* Stuart L. Nightingale, Joanna M. Prasher & Stewart Simonson, *Emergency Use Authorization (EUA) to enable use of needed products in civilian and military emergencies, United States*, Emerging Infectious Diseases (Jul. 13, 2007), available at https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article#r1.

B. The Context Shows an Intent to Uphold Informed Consent

Defendants’ interpretation of allowable “consequences” is further undercut by the legislative history and context in which this law was introduced. The universal human right of informed consent from coerced use of experimental medical products has been “firmly embedded” in U.S. law and FDA regulations for nearly 60 years. As the Second Circuit discussed at length in

Abdullahi , Congress first enacted this requirement in 1962 drawing on the Nuremberg Code and the Helsinki Declaration, “which suggests the government conceived of these sources’ articulation of the norm as a binding legal obligation.” 562 F.3d at 182. After American jurists codified the universal right to informed consent, particularly in the context of experimental medical products and devices, this *jus cogens* norm was then incorporated into the United States Code, the Code of Federal Regulations, and guidance from federal health agencies. Informed consent requirements are a cornerstone of FDA rules governing human medical experimentation. See e.g., 21 U.S.C. § 360bbb-0a (Even for patients with a life-threatening condition, an unlicensed medical product cannot be coerced, rather Congress required obtaining the patient’s “written informed consent.”) 42 U.S.C. § 9501 (Same for mental health patients);⁶ 45 C.F.R. § 46.116 (For an unlicensed medical product, the “Basic elements of informed consent” include that “participation is voluntary,” “refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled” and that consent be obtained without “coercion or undue influence.”);⁷ FDA Information Sheet: Informed Consent (“Coercion occurs when an overt threat of harm [such as expulsion from school or loss of employment] is intentionally presented by one person to another in order to obtain compliance.”)⁸ See, also, 21 C.F.R. §§ 50.23-.25, 50.27, 312.20, 312.120 (2008); 45 C.F.R. §§ 46.111, 46.116-117. The principle that individuals should not be coerced to receive an unlicensed medical product is also codified in the law of at least 84 countries and is an accepted principle of international common law. See, e.g., *Abdullahi*, 562 at 184.

⁶ See also 38 U.S.C. § 7331 (Same for veterans); 42 U.S.C § 300ff-61 (“in testing for HIV/AIDS, the applicant will test an individual only after the individual confirms that the decision of the individual with respect to undergoing such testing is voluntarily made”).

⁷ See also 21 C.F.R § 50.20 (sets forth conditions for obtaining informed consent for use of an unlicensed medical product and reiterating that consent should be free from “coercion or undue influence”)

⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#coercion>

It is unthinkable that in drafting Section 564, which governs the administration of products defined by statute as experimental medical products, that Congress intended to violate fundamental human rights laws by adding an informed consent requirement that allows for coercion so long as a person is informed that they may be coerced to accept an EUA product against their will. Indeed, federal court precedent establishes that even members of the U.S. military may not be coerced to accept EUA products. For example, the Department of Defense “may not require a member of the armed services to receive an “investigational new drug or a drug unapproved for its applied use.” *Bates v. Donley*, 935 F. Supp. 2d 14, 17 (2013). *See, also, Doe #1 v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) (“[T]he United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs.”; *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 19 (D.D.C. 2004) (solitary confinement and other coercive conditions cannot be imposed for refusing an EUA product). Certainly, a disabled child who cannot medically tolerate the experimental medical product (as certified by her physician) should not be coerced under this statutory scheme.

C. Legislative History Shows Congress Intended to Uphold International Informed Consent Requirements.

The legislative history shows that Congress intended to uphold the universally recognized right to informed consent from coercion to use experimental medical products. For example, on July 16, 2003, in deliberating Section 564, Representative Hays said, without any objection, that, “...any authority to actually use experimental drugs or medical devices in emergency situations has to be defined and wielded with nothing less than surgical precision. Prior informed consent in connection with the administration of experimental therapy is a basic human right, a right no one

should be asked to surrender...”⁹ Similarly, on May 19, 2004, Senator Kennedy said while deliberating regarding Section 564 that “[t]he authorization for the emergency use of unapproved products also includes strong provisions on informed consent for patients.”¹⁰

D. Agency Interpretations Consistently Acknowledge that EUA Products Cannot be Mandated.

The FDA itself takes the position that the terms and conditions governing EUAs preempt state and local laws. *See* 21 U.S.C. § 360(k)(a), “GENERAL RULE Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement that would impose obligations that are inconsistent with those terms and conditions.” *See, also*, Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders at 39-40 available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-useauthorization-medical-products-and-related-authorities>:

“FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564...To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular medical product within the scope of the

⁹ <https://www.congress.gov/congressional-record/2003/7/16/house-section/article/h6908-1>.

¹⁰ <https://www.congress.gov/congressional-record/2004/05/19/senate-section/article/S5744-1>. This same Senator also reiterated that Section 564 “allows the FDA to authorize the emergency use of medicines under the tightly controlled conditions outlined in this legislation.” *Id.* Those conditions are, of course, specifically outlined in Section 564. In a congressional hearing on Section 564 held a few months later, Representative Maloney added that “unapproved drugs and devices, whose risks and benefits are not fully tested, impose an unprecedented responsibility on the government. The FDA must be vigilant in protecting the public against unnecessary risks from these products. In part because of these concerns, the bill has been modified to require that health care providers and patients be informed that the products have not been approved and of their risks. ... These conditions [in Section 564] are essential for the safe use of unapproved products, and they should be imposed in all cases, except in truly extraordinary circumstances.” <https://www.congress.gov/congressional-record/2004/07/14/house-section/article/H5721-3>

declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’ and ‘conflicts with the exercise of Federal authority under [§ 564].’”

The individual EUA conditional letters affirm this commitment to honoring uncoerced informed consent (or refusal to consent) to use EUA products. Section 564 directs FDA to impose “[a]ppropriate” conditions on each EUA. FDCA § 564(e)(1)(A), including to ensure recipients “are informed” of the “the option to accept or refuse administration of the product.” *Id.* § 564(e)(1)(A)(ii)(III). As noted in the Complaint, all of the governing EUA conditional letters expressly require informed consent for the use of the available masks. Pursuant to the FDA’s own guidance, states may not issue regulations or requirements that stand in the way of the FDA’s conditions on use. The FDA recognizes that the only exception to the right arises in the context of national security and is limited to allowing coerced use of an EUA product on the military if the President signs a waiver. *See, also*, Nightingale SL, Prasher JM, Simonson S. Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States. *Emerging Infectious Diseases*. 2007;13(7):1046. doi:10.3201/eid1307.061188 available at https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article#r1 (“as a general rule, persons must be made aware of their right to refuse the product (or to refuse it for their children or others without the capacity to consent) and of the potential consequences, if any, of this choice. An exception to this rule is that the president, as commander in chief, can waive military personnel’s right to refuse this product. If the right is not specifically waived by the president for a particular product given under EUA, military personnel have the same right to refuse as civilians.) The FDA thus makes clear that Section 564 provides a substantive right to refuse, and this right does not exist in the presence of a requirement that imposes negative consequences for refusing.

Similarly, the CDC’s Advisory Committee on Immunization Practices (“ACIP”) has interpreted Section 564 as a consent provision and not merely a requirement to inform. When responding to an inquiry regarding whether the COVID-19 vaccines can be required, the Executive Secretary of ACIP publicly stated that “under an EUA, vaccines are not allowed to be mandatory. Therefore, early in the vaccination phase individuals will have to be consented and cannot be mandated to be vaccinated.”¹¹ ACIP’s Executive Secretary then reaffirmed to the FDA’s Vaccine and Related Biological Products Advisory Committee that no organization, public or private – including hospitals – can mandate the EUA COVID-19 Vaccines.¹²

Defendants cite to inapposite cases to attack Plaintiffs’ standing to enforce their right to refuse EUA products. The cases cited do not hold that “only the United States itself can file a suit challenging an FDCA violation.” On the contrary, the cases reveal that standing is highly dependent on the provision of the FDCA challenged. For example, *Buckman* and its progeny stand for the holding that state claims asserting that manufacturers committed fraud against the FDA are preempted because FDA already has a scheme in place to punish and deter fraud. *Frei v. Taro Pharms U.S.A., Inc.*, 443 F.Supp.3d 456,467 (S.D.N.Y. 2020) (discussing *Buckman Co v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001)). But these arguments cannot be extended to the requirements of Section 564, which articulates a private right to informed consent.

IV. Plaintiffs’ ADA and Rehabilitation Act Claims Survive Because Plaintiffs are Not Required to Exhaust their Administrative Remedies Before Bringing Suit

Plaintiff pleads viable claims under Title II of the Americans with Disabilities Act (“ADA”),

¹¹ <https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf> at 56.

¹² <https://www.fda.gov/media/143982/download> at 156.

42 U.S.C. §2101 et seq. (“Title II”) and Section 504 of the Rehabilitation Act of 1973 (“Section 504”), 29 U.S.C. §794, et seq. Plaintiffs allege, and Defendants do not dispute, that Sarah is a disabled child pursuant to the statutory definition, that her disabilities prevent her from wearing a mask, and that nonetheless, the school district failed to reasonably accommodate her in accordance with their responsibilities under Section 504 and Title II.¹³ Plaintiffs further assert that Sarah can be safely accommodated without posing a direct threat to those around her. These factual claims must be credited to her at this stage. Plaintiffs also allege that Defendants discriminated against whole categories of disabled children including Sarah in summarily denying her request in bad faith and then retaliated against her. Plaintiff has made a prima facie case that reasonable accommodation can be achieved. The burden thus falls to Defendants to persuade the Court that they were unable to accommodate her for a legitimate reason. This “is a fact-specific inquiry that generally does not lend itself to summary judgment.” *Brown v. Cty. of Nassau*, 736 F. Supp. 2d 602, 622 (E.D.N.Y. 2010). Moreover, Defendants (state and local) admit that they discriminated against whole categories of disabled children based on generalized statements on a CDC webpage. [Gibson Decl. Ex. 3].

State Defendants assert that since the Mandate specifically requires compliance with the ADA and Section 504, only the District is liable for these claims. However, as the Court noted in oral argument, the Mandate also requires schools to consider exemptions in light of “CDC exceptions” which are confusing and lead to discriminatory determinations. For example, both the

¹³ The District’s reluctant agreement to accommodate Plaintiff only after litigation commenced and expressly in order to avoid a hearing and adverse decision on the preliminary injunction motion does not moot Plaintiffs claims. Nor does the removal of the mask Mandate a few weeks ago. “It is well settled that “a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice.” *Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.*, 528 U.S. 167, 189, 120 S. Ct. 693, 708, 145 L. Ed. 2d 610 (2000). Moreover, Sarah’s protection from arbitrary reversal of accommodation is tenuous, and based largely on this Court’s order that her accommodation remain in place pending further order of the Court.

State and District admitted to blanket conclusion that pursuant to the Mandate, which requires District's to follow the "CDC's recommendations" related to accommodation, children with asthma cannot be accommodated, nor can any other child other than a paraplegic according to the CDC's standards. [Transcript - Gibson Decl. Ex. B pp 22-24]. But pursuant to statute, whether a person has a disability under the ADA and Section 504 is an individualized inquiry based on whether a person's disabilities collectively or singly impact major life activities. *See, Bragdon v. Abbott*, 524 U.S. 624, 641-642 (1998). Blanket rejections of whole categories of children, including children who suffer from asthma, falls afoul of the statutory scheme and gives rise to a discrimination claim against the State as well as the District.

District Defendants rely principally on the assertion that Plaintiff is barred from relief under the ADA and Section 504 because she failed to "exhaust" administrative remedies before filing suit. But the Supreme Court recently clarified that exhaustion is not necessary in discrimination and denial of reasonable accommodation claims brought under Title II of the ADA and Section 504. *Fry ex rel. E.F. v. Napoleon Cmty. Schs.*, 137 S. Ct. 743 (2017); *Patrick v. Success Acad. Charter Sch., Inc.*, 354 F. Supp. 3d 185, 227 (E.D.N.Y. 2018) (quoting *Fry*, 137 S. Ct. at 754–55) ("if a school 'refus[ed] to make an accommodation' for a disabled child, 'injuring [the child] in ways unrelated to a FAPE,' a plaintiff 'seeking redress for those other harms ... is not subject to § 1415(l)'s exhaustion rule.'")

Defendants cite to inapposite cases involving IEPs, not the failure to accommodate or discrimination claims that make up the gravamen of this complaint. *Camac v. Long Beach City Sch. Dist.*, 2011 WL 3030345 (E.D.N.Y. July 22, 2011) (predating *Fry* and concerning an IEP not failure to accommodate/discrimination claim); *Moskowitz, S.G. v. Success Acad. Charter Sch., Inc.* 18 Civ.

2484 at *28 (KPF) (S.D.N.Y. Mar. 20, 2019) (“[p]laintiffs' claims based on failure to implement an IEP mandate for a consistent paraprofessional or testing accommodations are subject to the IDEA's exhaustion requirement. Plaintiffs' remaining claims are not.” Remaining claims included “allegations of intentional discrimination, denial of reasonable accommodations, and violation of constitutional rights.”)

V. Notice of Claim Requirements Should Not Bar Plaintiffs State Claims

In *Margerum v. City of Buffalo*, 24 N.Y.3d 721 (2015), the New York Court of Appeals held that a notice of claim need not be filed for New York State Human Rights Law claims against a municipality. “Preliminarily, we reject the City's argument for dismissal on the basis of plaintiffs' failure to file a notice of claim prior to commencement of this action ... Human rights claims are not tort actions under section 50-e and are not personal injury, wrongful death, or damage to personal property claims under section 50-i. Nor do we perceive any reason to encumber the filing of discrimination claims. Accordingly, we conclude that there is no notice of claim requirement here.” *Id.* at 730.

Dispute exists about the applicability of *Margerum* to notice of claim requirements against school districts in light of N.Y. Educ. Law. § 3813(1) (“Education Law”). Courts in the Second Circuit are divided on whether a notice of claim is required for such claims against school districts. For example, in *Caputo v. Copiague Union Free Sch. Dist.*, 218 F. Supp. 3d 186 (E.D.N.Y. 2016), Judge Hurley stated “[a] notice of claim for a NYSHRL claim *against a school district* or its personnel is not required.” (emphasis added). However, other cases, like those cited by Defendants, read *Margarum* more narrowly, and would impose a notice of claim requirement. To the extent that the Court resolves in favor of Defendant, Plaintiffs respectfully assert that the state

law claims against the District should be dismissed without prejudice, since the Education Law has liberal standards for requesting leave to file a late notice of claim that Plaintiff easily meets, though Plaintiff must seek such leave in state court not federal. *See, e.g., Washington v. Borough of Manhattan Cmty. Coll.*, No. 16 CIV. 6168 (PAE), 2016 WL 7410717, at *2 (S.D.N.Y. Dec. 21, 2016) (Washington can return to federal court with her NYCHRL and NYSHRL claims if she has made application to the appropriate state court for leave to file a late notice of claim and that request has been granted and such a notice has been filed. Accordingly, the Court dismisses her NYCHRL and NYSHRL claims without prejudice) (citations omitted).

CONCLUSION

For all the reasons stated herein, Plaintiffs respectfully urge this Honorable Court to deny Defendants' Motions, and Order Defendants to answer the Amended Complaint.

Dated: Ithaca, New York
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